

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

LUANN PARKER,

Plaintiff,

v.

AVENTIS PASTEUR INC.,

Defendant.

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Case No. C-1-00-766

Judge Susan J. Dlott

MOTION FOR SUMMARY

JUDGMENT OF DEFENDANT

AVENTIS PASTEUR INC.

Defendant Aventis Pasteur Inc. (“Aventis” or “Defendant”) respectfully moves the Court pursuant to Rule 56 of the Federal Rules of Civil Procedure, for an order granting it summary judgment and dismissing plaintiff Luann Parker’s claims in their entirety because she is unable to come forward with reliable expert testimony establishing that Defendant’s FLUZONE® influenza vaccine caused her to suffer from a neurological disorder known as acute disseminated encephalomyelitis (“ADEM”) or any other injuries. A Memorandum in Support of this Motion which explains why summary judgment is warranted has been simultaneously filed with the Court.

Respectfully submitted,

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Counsel for Defendant Aventis Pasteur Inc.

CERTIFICATE OF SERVICE

The undersigned attorney for Aventis certifies that a copy of the foregoing Motion for Summary Judgment of Defendant Aventis Pasteur Inc. was served via the Court's electronic filing system upon Firooz T. Namei, Esq., and Roger W. Weseli, Esq., McKinney & Namei Co., L.P.A., 15 East Eighth Street, Cincinnati, Ohio 45202, counsel for Plaintiff, this 1st day of June, 2004.

/s/ Michael A. Snyder
An Attorney for Defendant Aventis Pasteur Inc.

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

LUANN PARKER,)	
)	Case No. C-1-00-766
Plaintiff,)	
)	Judge Susan J. Dlott
v.)	
)	MEMORANDUM IN SUPPORT OF
AVENTIS PASTEUR INC.,)	MOTION FOR SUMMARY
)	JUDGMENT OF DEFENDANT
Defendant.)	AVENTIS PASTEUR INC.

I. INTRODUCTION

This is a product liability case in which plaintiff, Luann Parker (“Plaintiff” or “Parker”), has alleged her receipt of an influenza vaccine manufactured by defendant Aventis Pasteur Inc. (“Aventis” or “Defendant”) caused her to suffer from a neurological condition. However, when a plaintiff’s theory of medical causation in this type of case is “unconfirmed by epidemiologic proof,” it cannot form the basis for causation in a court of law. Brock v. Merrill Dow Pharmaceuticals, 824 F.2d 307, 315 (5th Cir. 1989), modified by 884 F.2d 106 (5th Cir. 1989), Cert. Denied, 494 U.S. 1046, see also Conde v. Velsicol Chemical Corp., 804 F.Supp. 972, 1025-26 (S.D. Ohio 1992), affirmed, 24 F.3d 809 (6th Cir. 1994) (“epidemiologic studies are the primary generally accepted methodology for demonstrating a causal connection between a chemical compound and a set of symptoms or disease.”) So it is in this case. Since Plaintiff’s expert agrees there is no epidemiologic evidence linking the influenza vaccine to Plaintiff’s alleged injuries, Plaintiff is unable to prove the causation element of her claim.

Accordingly, Defendant Aventis Pasteur Inc. (“Aventis” or “Defendant”) respectfully moves the Court pursuant to Rule 56 of the Federal Rules of Civil Procedure, for an order

granting it summary judgment and dismissing plaintiff Luann Parker's claims in their entirety because Plaintiff is unable to come forward with reliable expert testimony demonstrating that Defendant's FLUZONE[®] influenza vaccine caused her to suffer from a neurological disorder known as acute disseminated encephalomyelitis ("ADEM") or any other injuries.

II. RELEVANT FACTS

A. Miss Parker and the Vaccination.

Plaintiff filed her Complaint against Aventis on September 12, 2001, in which she asserts claims sounding in strict products liability, failure to warn, and breach of implied warranty. All of Plaintiff's claims are based upon the allegation that Plaintiff was vaccinated with Defendant's FLUZONE[®] influenza vaccine and the vaccine caused the onset of ADEM.

On Friday, October 9, 1998, Plaintiff received a FLUZONE[®] intramuscular vaccination administered by Jennifer Leppert, a nurse employed by Comprehensive Health Care Services, Inc. ("Comprehensive") (Plaintiff's Complaint at ¶15.) Ms. Leppert administered the vaccine to Plaintiff at a Thriftway Supermarket, 4900 Hunt Road, Cincinnati, Ohio. (Plaintiff's Complaint at ¶20.) Ms. Parker remembers receiving the shot around 4:00 or 5:00 p.m. (Parker Dep. at p. 80.)

Prior to receiving her flu shot in 1998, Plaintiff had received flu shots annually for a six or seven year period. (Parker Dep. at p. 51.) Plaintiff suffered no adverse affects from these prior flu shots. (Parker Dep. at p. 61.) At the time she received the shot in 1998, Plaintiff was taking medicine for diabetes and blood pressure. (Parker Dep. at p. 79.)

Plaintiff alleged to have some problems the weekend following that Friday after she received the vaccination. Plaintiff testified that she was "fine" Saturday. (Parker Dep. at p. 84.) Her alleged symptoms began Saturday night. Plaintiff claimed to have had a "bad day" on Sunday. (Parker Dep. at p. 85.) Back in 1998, Plaintiff's mother was at Mercy Christian Village in Southern Ohio. (Parker Dep. at p. 86.) Typically, Plaintiff would be able to take her mother home with her on weekend days. On this Sunday, however, Plaintiff was not permitted to leave with her mother because of her mother's condition. (Parker Dep. at p. 84.) In fact, Sunday was

the last time Plaintiff would see her mother. (*Id.*) Plaintiff testified that she was very upset because of the condition of her mother. (*Id.*)

Following that weekend, Ms. Parker alleges that she began to suffer emotional and neurological problems. These problems necessitated her being hospitalized on and off in the ensuing months. (Complaint, *passim*) Plaintiff appears to have recovered, for the most part, from her neurological and psychiatric conditions as the last time Ms. Parker was treated by a psychiatrist or psychologist for her condition was back in 1999. (Parker Dep. at p. 120.) Since then, Ms. Parker has also not been on any medication for the neurological condition she alleges was caused by FLUZONE[®]. (Parker Dep. at p. 120.)

B. FLUZONE[®] Vaccine.

Influenza, commonly referred to as “the flu,” is a viral illness caused by the influenza virus. Epidemics of influenza typically occur during the winter months and are responsible for an average of 20,000 deaths per year in the United States. (“Prevention and Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP),” Morbidity and Mortality Weekly Report, Vol. 51, April 12, 2002.) Influenza vaccination is the primary and most effective method for preventing influenza and its severe complications. (*Id.*)

FLUZONE[®] is an FDA approved vaccine manufactured by Defendant Aventis Pasteur Inc. Each vial of FLUZONE[®] is accompanied by an insert detailing the warnings, contraindications and adverse reactions that might accompany the administration of FLUZONE[®].¹

¹ Aventis may also be entitled to summary judgment because FLUZONE[®] is an “unavoidably unsafe” drug under Ohio law that was distributed with a detailed warning. However, this defense does not come into play in this instance because Plaintiff has failed to establish her affirmative case by showing a “causal relationship” between FLUZONE[®] and her injuries. Graham v. American Cyanamid, 350 F.3d 496, 513 (6th Cir. 2003).

C. Plaintiff's Expert Witness: David Griesemer, M.D.

Plaintiff is required to prove causation with expert testimony due to the complex nature of this matter. To this end, Plaintiff has identified one expert witness, pediatric neurologist David Griesemer. Defense counsel deposed Dr. Griesemer on July 16, 2003, and a transcript of Dr. Griesemer's deposition was filed with the Court on May 20, 2004. Griesemer's deposition testimony demonstrates that his opinion is insufficient to prove causation because his opinion is based on nothing more than a temporal correlation between the Plaintiff's inoculation and the onset of symptoms of her purported neurological disorder. Griesemer's opinion is not supported by epidemiological studies or other reliable scientific or medical data.

Dr. Griesemer's deposition began with an admission that he has never written any articles on ADEM, and that his familiarity with the disease comes from diagnosing it "from time to time." (Griesemer Dep. at pp. 15, 17.) To this end Griesemer stated:

I have no particular expertise concerning ADEM that exceeds that of any good neurologist with a broad exposure to clinical disorders.

(Griesemer Dep. at pp. 15-16.)

Furthermore, with regard to the basis for his opinion that FLUZONE[®] caused Plaintiff to suffer from ADEM, Griesemer admits that he has not examined the Plaintiff, has never spoken to her, and has not reviewed her MRIs, CT scans, or other medical diagnostic test data. (Griesemer Dep. at p. 21.)

According to Griesemer, ADEM is

a disorder that involves demyelination in regions of the brain. It is a disorder that is typically monophasic, meaning it's got one phase to it, in distinction to a disorder like multiple sclerosis that also involves demyelination of the brain that has multiple occurrent phases to it.

(Griesemer Dep. at p. 21.) Griesemer further opines that “ADEM is typically a disorder that follows a viral infection or vaccination.” (Griesemer Dep. at p. 22.) However, Griesemer admits that he did not review or rely upon any scientific, medical or epidemiological studies or literature in formulating his opinion. (Griesemer Dep. at p. 24.) More importantly, Griesemer confirmed on multiple occasions that he is not aware of any epidemiological studies linking the influenza vaccine and ADEM, or establishing a causal relationship between them.

Q. You're not aware of any epidemiological study in peer reviewed medical literature that has ever indicated that there's a cause and effect relationship between influenza vaccine and ADEM?

A. That's correct.

(Griesemer Dep. at p. 30, see also pp. 24, 29, 34.) Furthermore, Griesemer admitted that he has never treated anyone that has contracted ADEM after receiving an influenza vaccine.

(Griesemer Dep. at p. 29.)

When asked to explain the basis for his opinion that Defendant's FLUZONE[®] vaccine caused the Plaintiff to suffer from ADEM, Griesemer repeatedly relies upon the temporal relationship between the Plaintiff's receipt of the vaccine and the initial onset of illness two days later. (Griesemer Dep. at pp. 29, 30, 31, 34-35) Griesemer further states that his opinion is based upon “clinical experience that says, in most cases, ADEM follows viral illness or vaccination” and the fact that he was not aware of any facts which indicate that the Plaintiff had a viral illness or a vaccination other than the FLUZONE[®] vaccination prior to displaying symptoms of ADEM². (Griesemer Dep. at pp. 30-31.) When pushed to support his opinion on causation during deposition, Griesemer stated that it was based upon the “preponderance of

² A nearly identical expert opinion was excluded by a court in a similar influenza vaccine case. See Lopez v. Wyeth-Ayerst Laboratories, 1996 U.S. Dist. LEXIS 22739 (N.D. Ca. 1996), affirmed, 139 F.3d 905 (1998).

medical literature” and his experience. (Griesemer Dep. at p. 31.) However, he thereafter admitted that he had not reviewed any studies or medical literature on the influenza vaccine and ADEM and then stated that his opinion was only based upon “current standards of clinical practice.” (Griesemer Dep. at p. 32.) Moreover, he once again admitted that there are no pathological or epidemiological evidence or studies available which demonstrate that the influenza vaccine could cause ADEM in general, or that it caused Plaintiff to suffer ADEM in this case. (Griesemer Dep. at p. 33.) To this end, Griesemer admitted that his conclusion on causation “does not adhere to the scientific level of proof that [he] would submit to a peer reviewed journal for publication.”³ (Griesemer Dep. at p. 33.)

When reviewed in its totality, it is clear that Griesemer’s opinion is based primarily on the temporal relationship between the Plaintiff’s receipt of the vaccine and the purported onset of symptoms of ADEM two days later, and lacks any sound epidemiological, medical or scientific support. (Griesemer Dep. at p. 34.) In fact, Griesemer admitted that the temporal relationship was an “important” factor in forming his opinion on causation. (Griesemer Dep. at p. 35.) Griesemer based his opinion on his belief that there had to be a “trigger” for the onset of ADEM, such as a viral infection or vaccination. However, he again readily admitted that he was unaware of any epidemiology demonstrating that vaccines of any type, let alone FLUZONE[®] or any influenza vaccine, can cause ADEM. (Griesemer Dep. at pp. 35-36) Griesemer’s entire opinion on causation is grounded upon his belief that ADEM only occurs after viral infection or vaccinations. However, Griesemer was unable to substantiate his opinion with anything more than the temporal relationship between the vaccination and the onset of symptoms. (Griesemer

³ When an expert admits that he would not subject his theory or opinion to peer review; courts should be suspicious because peer review is a component of good science, the same is true when an expert, like Griesemer, attempts to differentiate between scientific opinions on causation and medical-legal opinions on causation. See Allen v. Pennsylvania Engineering Corp., 102 F.3d 194, 198 (5th Cir. 1996).

Dep. at p. 45.) In fact, Griesemer went so far as to admit that there probably is not sufficient data or evidence to establish a cause and effect relationship between the influenza vaccine and ADEM. (Griesemer Dep. at p. 49.) When pushed, the only support that Griesemer could offer for his opinion, outside of the temporal relationship between the vaccination and the onset of symptoms, was an unsupported passing reference in a neurology textbook which states that ADEM can occur after vaccination against rabies, diphtheria, smallpox, tetanus, typhoid or influenza. (Griesemer Dep. at p. 80.)

D. Affidavit of Epidemiologist Paul Glezen, M.D.

As outlined above, Plaintiff's own expert neurologist has admitted that he is not aware of any studies or epidemiology which establish the existence of a causal relationship between the influenza vaccine and ADEM. In addition, Defendant offers the affidavit of Paul Glezen, M.D. See Exhibit A. Dr. Glezen is a board certified epidemiologist that has spent a substantial portion of his career studying and writing about influenza vaccines. Dr. Glezen is familiar with the medical literature and epidemiological studies which address the adverse effects of the influenza vaccine. See Exhibit A, ¶¶ 1-2. Dr. Glezen confirms Dr. Griesemer's suspicion that there are no epidemiological studies which establish the existence of a causal link between the influenza vaccine (FLUZONE[®] or otherwise) and ADEM:

To the best of my knowledge, there are no epidemiological studies in existence today which establish a causal link between the influenza vaccine, including but not limited to the FLUZONE influenza vaccine produced by Defendant Aventis Pasteur Inc., and acute disseminated encephalomyelitis, a neurological disorder that is often referred to as ADEM.

See Exhibit A, ¶ 3. It is undisputed, therefore, that there is no epidemiological evidence establishing that influenza vaccine causes ADEM. Absent such evidence, plaintiff's action fails and must be dismissed.

III. LEGAL ANALYSIS

A. Standard for Summary Judgment.

Motions for summary judgment are governed by Rule 56 of the Federal Rules of Civil Procedure. Summary judgment is appropriate if no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). On a motion for summary judgment, the movant has the burden of showing that there exists no genuine issue of material fact, and the evidence, together with all inferences that can permissibly be drawn therefrom, must be read in the light most favorable to the party opposing the motion. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986).

The moving party may support the motion for summary judgment with affidavits or other proof or by exposing the lack of evidence on an issue for which nonmoving party will bear the burden of proof at trial. See Celotex Corp. v. Catrett, 477 U.S. 317, 324, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). On those issues for which it shoulders the burden of proof, the moving party must make a showing that is “sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party.” Calderone v. United States, 799 F. 2d 254, 259 (6th Cir. 1986) (quoting W. Schwarzer, Summary Judgment Under the Federal Rules: Defining Genuine Issues of Material Fact, 99 F.R.D. 465, 487-88 (1984)) (emphasis omitted). For those issues where the moving party will not have the burden of proof at trial, the movant “point []out to the district court...that there is an absence of evidence to support the nonmoving party’s case. Celotex, 477 U.S. at 325.

In responding to a summary judgment motion, the nonmoving party may not rest upon the pleadings but must go beyond the pleadings and “present affirmative evidence in order to

defeat a properly supported motion for summary judgment.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). The nonmoving party “must set forth specific facts showing there is a genuine issue for trial.” Fed. R. Civ. Pro. 56(e). If the defendant moves for summary judgment based on the lack of proof of a material fact, “the mere existence of a scintilla of evidence in support of plaintiff’s position will be insufficient” to overcome the summary judgment motion. Anderson, 477 U.S. at 252. Thus, “if the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (citations omitted).⁴

⁴ See Johnson v. City of Cincinnati, 39 F. Supp. 2d 1013, 1014-15 (S. D. Ohio 1999) (J. Dlott), see also E. W. Scripts Co. & Subsidiaries v. United States, 297 F. Supp. 2d 1018, 1019-20 (S. D. Ohio 2003) (J. Dlott) (Summary Judgment Standard).

B. Plaintiff is Required to Come Forward With Reliable and Admissible Expert Testimony Demonstrating that Defendant's FLUZONE[®] Vaccine Caused Her to Contract ADEM.

"It is axiomatic that a necessary element in all products liability cases is proof of a causal relationship between the alleged defect and the resulting injury." U.S. Aviation Underwriters, Inc. v. B.F. Goodrich Co., (2002), 149 Ohio App. 3d 569, 2002-Ohio-5429, citing Kelley v. Cairns & Bros., Inc. (1993), 89 Ohio App. 3d 598, 610.

In order to establish Defendant's liability on any of her claims, Plaintiff is required to prove by a preponderance of the evidence that Defendant's vaccine is the direct and proximate cause of her injuries. In order to prove strict liability in tort, Parker must prove that her injuries were directly and proximately caused by the product defect. R.H. Macey & Co., Inc. v. Otis Elevator Co., 51 Ohio St. 3d 108 (1990). That is, Parker must demonstrate both that FLUZONE[®] is capable of causing the injuries she alleges (onset of ADEM) and that FLUZONE[®] did indeed cause her injury in this case (general causation and specific causation). See Bouchard v. American Home Products Corp., 213 F. Supp. 2d 802, 806 (N.D. Ohio 2002). Plaintiff is likewise required to prove causation in order to prevail on her failure to warn and implied warranty claims. See White v. Depuy, Inc. (1998), 129 Ohio App. 3d 372, 480-81 (breach of implied warranty claim requires proof that defect was direct and proximate cause of plaintiff's injuries), Graham v. American Cyanamid Co., 350 F. 3d 507, 513-14 (6th Cir. 2003), (failure to warn or inadequate warning claims require proof of causation).

The Sixth Circuit Court of Appeals recently addressed issues similar to those in this case in a products liability case involving personal injuries that were allegedly caused by a polio vaccine in Graham, where it held that in order "to establish strict liability under Ohio law, plaintiffs must produce expert testimony that the defect at issue proximately caused their claimed injuries." See Graham, 350 F. 3d at 507, 513. "In view of the technical and scientifically

complex nature of this inquiry, only Daubert-qualifying expert testimony may satisfy it.”

Graham, 350 F. 3d at 510. Since Aventis “does not bear the ultimate burden of persuasion on the causation issue [it] need only point out the lack of a genuine issue regarding causation” to obtain summary judgment. Elkins v. Richardson-Merrell, Inc., 8 F.3d 1068, 1071 (6th Cir. 1993). Lack of reliable expert opinion evidence may be the basis for a directed verdict or a grant of summary judgment if the evidence is insufficient to allow a reasonable juror to conclude [it is] more likely than not true.” Conde v. Velsicol Chemical Corp., 24 F. 3d 809, 812 (6th Cir. 1994), citing Elkins, at 1073.

C. The Daubert Standard.

In Daubert, 509 U.S. 579 (1993) the Supreme Court of the United States considered whether the former Frye⁵ test for determining expert opinion admissibility had been superseded by Fed. R. Evid. 702. The Court not only concluded that Frye had been superseded by the Rules of Evidence, but went on to articulate sweeping changes to the applicable standards for admitting expert opinions into evidence. As relevant here, the Daubert Court held that district courts have a “gatekeeping” role to determine whether proposed scientific expert testimony is both reliable and relevant. Id. at 597. In two subsequent decisions, the Supreme Court expanded and strengthened the district court’s duty to exclude unreliable expert testimony under Fed. R. Evid. 702. General Electric Co. v. Joiner, 522 U.S. 136, 118 S. Ct. 512 (1997) (clarifying that Daubert requires determination that expert’s conclusions rationally flow from available data); Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 119 S. Ct. 1167, 1174, (1999) (extending Daubert analysis to non-scientific expert testimony).

Under the gatekeeper duty articulated in Daubert, a trial court is required under Fed. R. Evid. 104(a) to answer preliminary questions regarding the admissibility of expert testimony under Fed. R. Evid. 702. A two-step inquiry is required to determine admissibility. First, the court must determine whether the expert’s testimony is reliable in that it reflects “scientific knowledge,” is “derived by the scientific method,” and amounts to “good science.” Daubert, 509 U.S. at 593. An expert opinion based on scientifically valid principles will satisfy Fed. R. Evid. 702, but an expert’s “subjective belief or unsupported speculation will not.” Smelser v. Norfolk Southern Ry. Co., 105 F.3d 299, 303 (6th Cir. 1997), cert. denied, 118 S.Ct. 67 (1997), quoting

⁵ The test enunciated in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), which predated the Federal Rules of Evidence by many years, focused on whether the scientific principles and methodology underlying the expert opinion had “general acceptance” in the relevant scientific community.

Daubert (on remand), 43 F.3d 1311, 1316 (9th Cir. 1995). Second, the court “must ensure that the proposed expert testimony is relevant to the task at hand.” Id. at 1315. The Supreme Court referred to this second step as the “fit” requirement. Id. When making a preliminary finding regarding an expert’s qualifications, the trial court must examine “not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” Smelser, 105 F.3d at 303.

With respect to the first step of the inquiry relating to “reliability”, the Daubert Court articulated a non-exclusive list of factors to be considered by trial courts in the inquiry. Those factors are:

- (1) whether the theory or technique can be (and has been) tested;
- (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error in using a particular scientific technique; and
- (4) whether the theory or technique has been generally accepted in the particular scientific field.⁶

In Daubert, the Court initially indicated that trial courts should focus solely on the expert’s “principles and methodology, not on the conclusions that they generate.” Daubert, 509 U.S. at 595. However, in a later decision, General Electric Co. v. Joiner, 522 U.S. 136, 118 S. Ct. 512 (1997), the Court clarified that the gatekeeper function is not limited solely to methodology as it indicated in Daubert, but also properly includes a review of the connection between the methodology and the expert’s conclusions:

[c]onclusions and methodology are not entirely distinct from one another...[n]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A

⁶ Id. at 591-94.

court may conclude that there is simply too great an analytical gap between the data and the opinion offered.⁷

In December 2000, Fed. R. Evid. 702 was amended to codify the general approach set forth in Daubert and its progeny. The Advisory Committee Note to the amended rule sets forth a list of additional factors which federal courts have applied in determining the reliability of expert opinions. The Sixth Circuit has recognized that expert opinions that are developed solely for purposes of litigation (as are the opinions offered by Plaintiff's expert), rather than as part of an expert's scientific research separate and apart from any litigation, deserve particularly stringent scrutiny under Daubert. Smelzer, 105 F.3d at 303.

⁷ Id. at 146, 118 S. Ct. at 519 (emphasis added).

**D. Dr. Griesemer's Testimony is Unreliable and Inadmissible
Under Daubert and its Progeny.**

Dr. Griesemer's testimony on causation is unreliable and inadmissible because (1) his opinion is not based upon epidemiological studies or other reliable scientific or medical data or methodologies that establish a causal link between FLUZONE[®], or any influenza vaccine, and ADEM; (2) his opinion is primarily based upon temporal relationships; and (3) his opinion is nothing more than a subjective and unsupported personal opinion that was sought for the purpose of litigation.

**1. Dr. Griesemer's Opinion on Causation is Unreliable Because it is not Based
Upon Epidemiological Studies or Other Reliable Scientific Data or Methodologies.**

Theories of toxic causation that are "unconfirmed by epidemiologic proof cannot form the basis for causation in courts of law." Brock v. Merrill Dow Pharmaceuticals, 874 F. 2d 307, 315 (5th Cir. 1989), modified by 884 F.2d 106 (5th Cir. 1989), Cert. Denied, 494 U.S. 1046 (1990), see also Allen v. Pennsylvania Engineering Corp., 102 F.3d 194, 195 (5th Cir. 1996) ("Where, as here, no epidemiological study has found a statistically significant link between EtO exposure and human brain cancer . . . the expert testimony does not exhibit the level of reliability necessary to comport with Federal Rules of Evidence 702 and 703, [and] the Supreme Court's Daubert decision . . . ").

Epidemiology is the branch of medicine that deals with the causes, distribution, and control of diseases in humans. Chambers v. Exxon Corporation, 81 F.Supp.2d 661, 664 (M.D. La. 2000). "Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it . . . to define that relationship, the epidemiologists examines the general population, comparing the incidence of the disease among those people exposed to the factor in

question to those not exposed. The epidemiologist then uses statistical methods and reasoning to allow her to draw a biological inference between the factor being studied and the diseases etiology.” Brock, 874 F.2d at 311.

“A long series of federal cases supports the legal principle that an expert medical opinion must have an epidemiological or scientific foundation to support a reasonable finding of fact. Many cases considered the pivotal issue of medical causation and held unsupported opinions inadmissible or insufficient to support a finding of fact.” Porter v. Whitehall Laboratories, Inc., 791 F.Supp. 1335, 1347-48 (S.D. Ind. 1992) (Collecting cases on this point and granting summary judgment to defendant manufacturer of ibuprofen). In fact, this Court has held that “[e]pidemiologic studies are the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease.” Conde v. Velsicol Chemical Corp., 804 F.Supp. 972, 1025-26 (S.D. Ohio 1992), affirmed, 24 F.3d 809 (6th Cir. 1994).

Dr. Griesemer offers the conclusory opinion that it is probable that Defendant’s influenza vaccine caused Plaintiff to suffer from ADEM. (Griesemer Dep. at p. 31.) However, Griesemer readily admits that his opinion is not grounded in the results of epidemiological studies or other reliable medical data which link the influenza vaccine to ADEM. Moreover, Griesemer states that he is unaware of whether any such studies or data even exist. Dr. Glezen, an epidemiologist and an expert in the influenza virus and influenza vaccine, who has studied, lectured on, and published on the subject, confirms that there are no epidemiological studies establishing a causal link between influenza vaccine and ADEM. See Exhibit A (Affidavit of Paul Glezen, M.D.).

The Sixth Circuit Court of Appeals, like the Fifth Circuit in Brock, has excluded expert opinions on causation in toxic tort and products liability cases when the opinion lacks

epidemiological support or otherwise fails to be grounded in a scientifically valid reasoning or methodology. For example, in Conde v. Velsicol Chemical Corp., 24 F. 3d 809 (6th Cir. 1994), the Court of Appeals affirmed this Court's exclusion of a plaintiffs' expert's opinion that the defendant's commercial termiticide caused the plaintiffs to suffer health problems because there were no epidemiological studies to establish either a negative or a positive association between exposure to the substance and carcinogenic risk. Conde, 24 F. 3d at 813-14. Moreover, in Turpin v. Merrill Dow Pharmaceuticals, Inc., 959 F. 2d 1349 (6th Cir. 1992), the Court affirmed a summary judgment ruling on behalf of defendants in a case in which the plaintiffs alleged that a pharmaceutical drug, Bendectin, caused their daughter's birth defects, because the scientific evidence available at the time did not establish a causal link between the use of Bendectin and birth defects. Finally, in Novak v. United States, 865 F. 2d 718 (6th Cir. 1989), the Court reversed a lower court's judgment for the plaintiff on the issue of whether the swine flu vaccine caused the plaintiff's husband to contract a disease where one of plaintiff's experts testified "that a theory of causal relationship...[was] not supported by any epidemiological studies," and the plaintiff failed to establish that clinical tests or another accepted medical basis supported their theory of causation. Novak, 865 F. 2d at 323.

This situation is no different here. Dr. Griesemer admitted that he is not aware of any epidemiological studies or other reliable scientific data establishing a causal link between the influenza vaccine and ADEM. Dr. Glezen confirms that there are no such studies. See Exhibit A. Accordingly, the Court should deem Dr. Griesemer's opinion on causation to be unreliable and inadmissible, and find that it cannot form the basis for causation in this case.

2. Dr. Griesemer's Opinion on Causation is Unreliable Because it is Based Primarily Upon the Temporal Correlation Between Plaintiff's Receipt of the Vaccine and the Onset of Illness.

As described above, a review of Dr. Griesemer's deposition testimony in its entirety reveals that the primary, and nearly sole, basis for his opinion on causation is the fact that the Plaintiff began to show signs of illness two days after being inoculated. In fact, Dr. Griesemer admitted that this temporal relationship was, in his words, an "important factor" in formulating his opinion on causation. (Griesemer Dep. at p. 35.) While Dr. Griesemer classifies this temporal relationship as an "important factor", he was unable to identify any other basis for his opinion, other than a passing reference in a textbook which indicated that ADEM may follow a viral infection or vaccination. "Generally, Courts have excluded expert causation testimony that is based upon such anecdotal or case reports. . . [because] they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." Lopez v. Wyeth-Ayerst Laboratories, 1996 U.S. Dist. LEXIS 22739 (N.D. Ca. 1996) (Granting summary judgment to influenza vaccine manufacturer on plaintiff's claims that vaccine caused neurological injury), affirmed, 139 F.3d 905 (9th Cir. 1998) (attached as Exhibit F), see also In re Breast Implant Litigation, 11 F. Supp.2d 1217, 1233 (D. Co. 1998) (rejecting opinion testimony based upon "clinical experience" and "review of the medical literature" and noting that the mere possibility of a causal relationship is insufficient for a causation opinion under Daubert).

Courts across the country have recognized that "an opinion based primarily, if not solely on temporal proximity does not meet Daubert standards." Roche v. Lincoln Property Co., 278 F. Supp. 2d 744, 764-65 (E.D. Vir. 2003), citing Cavallo v. Star Enterprise, 892 F. Supp. 756 (E.D.

Vir. 1995), affirmed in relevant part, 100 F. 3d 1150 (4th Cir. 1996), In re Breast Implant Litigation, 11 F. Supp. 2d 1217, 1232-33 (D.Col. 1998), In re Swine Flu Immunization Products Liability Litigation, 533 F. Supp. 567 (D. Col.1980), In re Agent Orange Products Liability Litigation, 611 F. Supp. 1223, 1249 (E. D. N.Y. 1985). The Second Circuit Court of Appeals recently affirmed a lower court's award of summary judgment to a defendant in a products liability case involving a vaccine because there were no epidemiological studies to support the plaintiff's expert's opinion and the opinion was based "largely on the temporal proximity" of the vaccination to the onset of symptoms. See Washburn v. Merck & Co., Inc., 2000 U.S. App. LEXIS 8601 (2nd Cir. May 1, 2000) (attached as Exhibit B). In doing so, the Washburn court affirmed the lower court's finding that the expert testimony on causation was not reliable because it was based on "little more than temporal correlation" and was therefore properly excluded because it was unsubstantiated. Washburn, *6. The Washburn court cited the opinions of the United States District Court for the Southern District of Ohio and the Sixth Circuit Court of Appeals in Conde for the proposition that expert testimony on causation is unreliable and inadmissible when it is based on little more than temporal correlation. See Conde, 804 F. Supp. 972, 1023 (S.D. Ohio 1992), affirmed 24 F. 3d 809 (6th Cir. 1994).

In addition to its decision in Conde, the Sixth Circuit Court of Appeals has made similar rulings in a multitude of other cases. In Novak, the Court reversed an award of judgment for the plaintiff because the plaintiff failed to come forward with reliable expert testimony establishing that the swine flu vaccine caused the illness that killed the plaintiff's husband and the plaintiff's experts "relied heavily on the relatively short period between Novak's inoculation and development of his sickness". Novak, 865 F. 2d at 722. In doing so, the Novak Court cited its previous decision in another swine flu vaccination case, Hassler v. United States, 718 F. 2d 202,

205 (6th Cir. 1983), Cert. Denied, 469 U.S. 817 (1984), where it found that a temporal relationship could not support a finding of causation because any connection between the vaccination and illness was “merely conjectural.”

Dr. Griesemer’s expert opinion on causation is unreliable and inadmissible since it is based primarily upon the temporal correlation between Parker’s receipt of the vaccination and the onset of signs of illness two days later.

3. Dr. Griesemer’s Opinion on Causation is Unreliable Because it is Merely an Unsupported Statement of Personal Opinion.

Dr. Griesemer was unable to substantiate his opinion on causation with anything more than a single unsupported reference in a medical textbook, and the temporal relationship discussed herein. Griesemer’s deposition testimony demonstrates that his opinion is grounded in little more than his subjective personal opinion and is not supported by any sound scientific or medical methodology or epidemiology.

“An admissible expert’s opinion, it is clear, must be supported by more than subjective belief and unsupported speculation.” Graham, 350 F. 3d at 510, see also Turpin, 959 F. 2d at 1360 (Sixth Circuit finds that expert opinion lacking demonstrated scientific basis was nothing more than subjective personal opinion and is inadmissible.)

Merely because an opinion of scientific causation comes from a person learned in medical science does not provide that opinion with sufficient scientific basis. An expert cannot rely solely on his or her own stature, intellect or intuition to support an opinion admissible to aid the trier of fact . . . The factual basis of a particular medical conclusion is composed of an application of particular scientific facts to particular data about the instant case. Admissible opinions relate instant facts to known relationships; an opinion relating instant facts to an unknown relationship (a hypothesis) does not further the trier of facts ability to determine a fact dependent upon that hypothetical relationship. Although experts may provide opinions in the form of a hypothetical fact situation, the scientific foundation or reasoning process may not be based on merely hypothetical causal relationships.

Unsupported subjective opinion is unhelpful speculation and not admissible under Rule 702.

Porter, 791 F.Supp. at 1345 (emphasis added), see also Chambers, 81 F.Supp.2d at 665 (personal opinions, “albeit expert,” do not suffice as evidence). Dr. Griesemer’s opinion is not based upon the results of any epidemiological studies or other hard scientific/medical proof of a causal link between the influenza vaccine and ADEM. While Dr. Griesemer hypothesizes that Defendant’s FLUZONE vaccine caused Luann Parker to suffer from ADEM, he simultaneously admits that his opinion on causation is not the type of opinion or theory which would be sufficient for peer review. A similar opinion was offered by an expert witness in Allen and rejected by the court pursuant to Daubert. See Allen v. Pennsylvania Engineering Corp., 102 F.3d 194, 198 (5th Cir. 1996). Accordingly, Dr. Griesemer’s opinion testimony on causation is unreliable and inadmissible as it is merely his subjective personal opinion and is not grounded in science or medicine.

Plaintiff is required to carry the burden of coming forward with reliable expert opinion testimony establishing that Defendant’s FLUZONE[®] vaccine is capable of causing ADEM generally, and in fact caused her to suffer from ADEM in this instance. The only evidence that Plaintiff has marshaled on this point is the opinion testimony of Dr. Griesemer. Dr. Griesemer’s opinions on causation are unreliable and inadmissible for the reasons described herein. Accordingly, Aventis is entitled to summary judgment as a matter of law because Plaintiff is unable to carry her burden under Rule 56 of the Federal Rules of Civil Procedure by coming forward with reliable expert testimony that establishes causation.

E. Aventis is Entitled to Summary Judgment Because Dr. Griesemer's Opinion on Causation is Insufficient to Allow a Reasonable Jury to Find in Plaintiff's Favor.

Aventis urges the Court to exclude Dr. Griesemer's expert testimony on the issue of causation and award Aventis summary judgment pursuant to Daubert and its progeny, for the reasons described above. "The holding in Daubert, however, dealt only with the circumstances under which expert testimony is admissible, and not with the separate question of when such testimony is sufficient to submit a case to the jury." Conde, 24 F. 3d at 813. Assuming *arguendo*, that Dr. Griesemer's "expert opinion or evidence on one side [is] relevant and admissible, if [it is] insufficient to allow a reasonable juror to conclude that the position [is] more likely than not true, it may be the basis for a directed verdict or a grant of summary judgment." Conde, *Id.*, citing Elkins v. Richardson-Merrell, Inc., 8 F. 3d 1068, 1073 (6th Cir. 1993) (quoting Daubert), Cert. Denied, 510 U.S. 1193 (1994). Therefore, in the event that the Court should find Dr. Griesemer's expert testimony on causation to be admissible, Aventis is still entitled to summary judgment as a matter of law because Dr. Griesemer's testimony is legally insufficient to allow a reasonable juror to conclude that Defendant's influenza vaccine is more likely than not, the cause of Plaintiff's injuries.

Ms. Parker may not escape summary judgment merely by producing an expert witness whose testimony is insufficient to allow a reasonable jury to conclude in her favor because "the court remains free to prohibit the case from proceeding to the jury" under such circumstances. See Austin v. Children's Hospital Medical Center, 1996 U.S. App. LEXIS 22329 (6th Cir. 1996) (attached as Exhibit C), citing Glaser v. Thompson Medical Co., 32 F. 3d 969, 972 (6th Cir. 1994), see also Conde, 24 F. 3d at 812, see also Downs v. Perstorp Components, Inc., 2002 U.S. App. LEXIS 382 (6th Cir. 2002) (attached as Exhibit D), Wheeler v. Baptist Health Care System, Inc., 2001 U.S. App. LEXIS 16148 (6th Cir. 2001) (affirming summary judgment rulings for

defendants in products liability and medical malpractice cases due to the absence of reliable expert testimony for a plaintiff) (attached as Exhibit E). As discussed in detail herein, Dr. Griesemer's opinion testimony on causation lacks any epidemiological or other sound scientific or medical basis, as it is grounded primarily upon temporal correlation and his own subjective personal opinion. However, "expert testimony must be based on the evidence, so as to be removed from the realm of guesswork and speculation." Turpin, 959 F. 2d 1360, citing Calhoun v. Honda Motor Co., 738 F. 2d 126, 131-32 (6th Cir. 1984). Given the status of Plaintiff's expert testimony on causation in this case, no reasonable jury could conclude that Defendant's FLUZONE[®] influenza vaccine is capable of causing ADEM, and in fact caused the Plaintiff's illness, without relying upon guesswork and speculation as a basis for its findings. Dr. Griesemer's conclusion on causation "so overstates its predicate that...it cannot legitimately form the basis for a jury verdict...[because] the analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue...is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation." Turpin, 959 F. 2d at 1359-61. Accordingly, Aventis is entitled to summary judgment as a matter of law.

IV. CONCLUSION

Aventis respectfully moves the Court for an Order granting it summary judgment and dismissing Plaintiff's claims with prejudice for the reasons described herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned attorney for Aventis certifies that a copy of the foregoing Memorandum in Support of Defendant Aventis Pasteur Inc.'s Motion for Summary Judgment was served via the Court's electronic filing system upon Firooz T. Namei, Esq., and Roger W. Weseli, Esq., McKinney & Namei Co., L.P.A., 15 East Eighth Street, Cincinnati, Ohio 45202, counsel for Plaintiff, this 1st day of June, 2004.

/s/ Michael A. Snyder
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